

a housing for containing the optics system and holding the removable test strip in position relative to the optics system;

an optics block holder mounted in the electronics printed circuit board in alignment with the alignment fixturing, the optics block holder aligning the test strip to the test pad and positioning the optics system to focus light from the light emitter and to the detector; and

a processor in communication with the light detector, the processor controlling the assay system such that a predetermined number of test strips are assayed based on signals from the light detector, wherein the predetermined number corresponds to the number of test strips of a set of one or more test strips.

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#### REMARKS

Claims 8-19 were pending at the time of the instant Office Action. Claims 8 and 14 were rejected under 35 U.S.C. § 102(b) over European patent 0 573 598 to Grant et al. ("Grant" herein). Claims 9 and 15 were rejected under 35 U.S.C. § 103(a) as obvious over the combination of Grant and U.S. Patent No. 4,833,088 to DeSimone et al. ("DeSimone" herein). Claims 10, 12, 13, 16, and 19 were rejected under 35 U.S.C. § 103(a) as obvious over the combination of Grant and U.S. Patent No. 5,989,917 to McAleer et al. ("McAleer" herein). Claims 11 and 17 were rejected as obvious under 35 U.S.C. § 103(a) over the combination of Grant, McAleer, and DeSimone. Claim 18 was rejected under 35 U.S.C. § 103(a) as obvious over the combination of Grant, McAleer, and U.S. Patent No. 5,795,543 to Poto, et al., ("Poto" herein). Applicants traverse each rejection as discussed herein.

Applicants have amended claim 10 to correct a typographical error, and have resubmitted PCT Publication WO 98/19159 in a Supplemental Information Disclosure Statement enclosed herewith, in response to the Examiner's remark that no copy of that reference was included with the original IDS.

Among other things, claim 8 (amended) recites "a multi-use assay system for use with a removable test strip ... comprising: ... a processor in communication with the detector, the processor controlling the assay system in accordance with calibration information uniquely specific to a reagent associated with a set of one or more test strips." Apparently in connection with this element, the Office Action cites Grant, column 18, lines 45-58. That passage of Grant (discussing diagnostics that use "a special diagnostic ROM code key 64," from column 18, line 36 through column 20, line 37), however, neither shows nor suggests the recited "calibration information uniquely specific to a reagent associated with a set of one or more test strips." To the contrary, Grant teaches calibration using remissions from white tile 142 (see, e.g., column 9, lines 7-10; column 15, lines 11-12 and 40-42), but white tile 142 is attached to lift member 134 (column 9, lines 7-10), which is connected to carrier strip body 120 (column 8, line 56 – column 9, line 1), which is locked to case portion 100 (column 8, lines 44-49). White tile 142 is thus part of the testing unit, not ROM key 64, and nothing in Grant shows or suggests that white tile 142 provides "calibration information *uniquely specific* to a reagent associated with a set of one or more test strips" as recited in claim 8 (amended). While Grant suggests, "A new ROM key is packaged in every supply of strips 106," (column 17, lines 2-3), Grant only suggests that ROM key 64 contains data reflecting upper and lower thresholds for detecting problems with unused strips, but not for calibration itself (which according to Grant is

merely a function of readings from white tile 142, as discussed above). Thus, Grant neither shows nor suggests this element of claim 8, and the rejection of that claim (and claim 14, which depends therefrom) should be withdrawn.

Claim 9, which also depends from claim 8, and claim 15, which depends from claim 9, were rejected over the combination of Grant and DeSimone. Neither reference, however, shows or suggests “a processor” as recited in claim 8 and discussed above, nor the additional element recited in claim 9, “a removable calibration chip, *the* calibration information [recited in parent claim 8] being provided by the removable calibration chip.” While DeSimone uses the phrase “calibration chip”, DeSimone’s “calibration chip” does not meet this limitation, which requires “calibration information” (as the phrase is used in parent claim 8) to be provided thereby. In contrast, neither Grant nor DeSimone show or suggest a “calibration chip” that provides “calibration information” (claim 9) that is “uniquely specific to a reagent associated with a set of one or more test strips” (as recited in parent claim 8). Thus, the rejection fails to show all elements of claim 9, and does not provide a *prima facie* case of obviousness. The rejection of claims 9 and 15 (which depends from claim 9) should be withdrawn.

Claim 10 recites, among other things, “a processor ... controlling the assay system such that a predetermined number of test strips are assayed based on signals from the detector, wherein the predetermined number corresponds to the number of test strips of a set of one or more test strips.” The passage of McAleer cited in the Office Action, however, shows that the processor in McAleer generates an error signal if a counter *that is reset upon loading of a new container of strips* exceeds the original number of strips in the container. The fact that the counter is reset upon loading of a new container shows that the

light detector in McAleer is used for the assay of a number of test strips greater than the number of test strips in a set (compare the language from claim 10 quoted above). Because the reference is missing the “processor ...” element of claim 10, the rejection of claim 10 (and claim 16, depending therefrom) should be withdrawn.

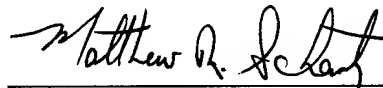
In addition, the Office Action presents no motivation *from the art* to combine Grant and McAleer to achieve the claimed combination. The Office Action suggests, “It would have been obvious to one having ordinary skill in the art at the time of invention to include a processor to control the system such that a predetermined number of test strips are tested to maintain proper and accurate testing of the test strip.” (Office Action, page 4.) The cited references, however, each include their own methods of maintaining proper and accurate testing. For example, Grant checks remissions of white tile 142 for dirtiness (Grant, column 17, lines 24-26), and checks remissions from unused strips against upper and lower limits in ROM key 64 (Grant, column 16, lines 4-8). Grant does not suggest adding other steps “to maintain proper and accurate testing ... .” Likewise, McAleer discusses some methods of managing use of the system (though, as discussed above, not the one recited in claim 10), but neither shows nor suggests combination with further measures. Because the required motivation is lacking from the cited art, the Office Action fails to present a *prima facie* case of obviousness as to claim 10, and rejection of claim 10 should be withdrawn.

The references cited in the Office Action discussion of claim 12 also lack the necessary motivation to combine them to achieve the claimed invention. As discussed above in relation to claim 10, Grant and McAleer each include their own, specified measures to improve reliability of the testing process. Given that Grant checks whether

tile 142 is dirty and checks unused strips for remissions within an acceptable range, there is no motivation for one skilled in the art to take additional measures that would limit the usefulness of the system by using a date to prevent testing, when the responsiveness of the strip is already being checked. Since these references must each be read as a whole (*see* MPEP § 214.02), the motivation required for a *prima facie* case of obviousness is absent from the art, and the rejection of claim 12 (and claims 13, 18, and 19, depending therefrom) should be withdrawn.

With the above amendment, and in light of the above remarks, it is believed that all pending claims are in condition for allowance. Timely action toward issuance is respectfully solicited.

Respectfully submitted,



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## ADDITIONAL VERSION TO SHOW CHANGES MADE

*Claim 10 was amended as follows:*

10. (Twice Amended) A multi-use assay system for use with a removable test strip having a test pad, the multi-use assay system comprising:
- an electronics printed circuit board having an alignment fixturing;
  - an optics system for alignment with the removable test strip, the optics system comprising a lens, an emitter and a detector, wherein the emitter and detector are mounted in the electronics printed circuit board relative to the alignment fixturing;
  - a housing for containing the optics system and holding the removable test strip in position relative to the optics system;
  - an optics block holder mounted in the electronics printed circuit board in alignment with the alignment fixturing, the optics block holder aligning the test strip to the test pad and positioning the optics system to focus light from the light emitter and to the detector;
  - and
  - a processor in communication with the light detector, the processor controlling the assay system such that a predetermined number of test strips are assayed based on signals from the light detector, wherein the predetermined number corresponds to the number of test[s] strips of a set of one or more test strips.